Overview of Fenthion Revised Risk Assessment

Introduction

This document summarizes EPA's human health and ecological risk findings and conclusions for the organophosphate pesticide fenthion, as presented fully in the documents, "Fenthion: The HED Chapter of the Reregistration Eligibility Decision Document (RED), Case #0290, PC Code 053301" dated April 16, 1998, "Fenthion. Revised Human Health Risk Assessment." dated March 5, 1999, "Human Health Risk Assessment - Fenthion" dated October 13, 1999 and "Transmittal of EFED RED for the List A Chemical Fenthion" dated May 1, 1996. The purpose of this overview is to assist the reader by identifying the key features and findings of these risk assessments and to better understand the conclusions reached in the assessments.

The revised human health and ecological risk assessments for fenthion will be posted on the Internet (http://www.epa.gov/oppsrrd1/op/fenthion) and placed in the Pesticide Docket on or about October 13, 1999, and a 60 day public participation period on risk management will begin.

EPA has determined that it is appropriate to treat the organophosphates (OPs) as sharing a common mechanism of toxicity: the inhibition of cholinesterase activity. As required by FQPA, a cumulative assessment will need to be conducted to evaluate the risk from food, water and non-occupational exposure resulting from all uses of OPs. Currently, the Agency is developing the draft methodology needed to conduct such an assessment with guidance/advice provided by the Science Advisory Panel. Consequently, the risks summarized in this document are only for fenthion.

Use Profile

- Insecticide: Registered for use as a mosquito adulticide in Florida only. (There are also three granular mosquito larvicide products which are registered but are rarely used in the U.S.) Also registered to control lice, flies, and ticks on cattle and swine. State registrations exist in Florida, Arkansas, and Missouri to control dragonfly larvae in ornamental fishponds (aquaculture). Rid-A-Bird, an avicide product, is cancelled.
- **Formulations:** Fenthion is formulated into the following types of products: emulsifiable concentrate; granulars; impregnated material ear tag; soluble concentrates; and liquid ready-to-use (RTU) solutions.

• Methods of Application:

Mosquito control use: ground and aerial.

<u>Livestock use</u>: ear tags, spot treatment, and pour-on applications. Ear tags are registered to control face flies, horn flies, and gulf coast ticks. Pour-on and spot treatments are registered to control horn flies and lice. (*Lactating* dairy cattle can be treated with ear tags <u>only</u>. Non-lactating dairy cattle and beef cattle can be treated with ear tags, spot, or pour-on treatments. Swine are treated with spot or pour-on treatments.)

<u>Aquaculture</u>: handheld equipment such as low pressure hand wand sprayers and backpack sprayers.

• Use Rates:

<u>Livestock use</u>: ear tag = 0.2 oz ai/animal = 2 tags per animal (for beef and dairy cattle); spot treatment = 0.02 oz ai/100 lbs body weight (for beef cattle, non-lactating dairy cattle, and swine only); pour-on treatment = 0.082 oz ai/100 lb body weight (for beef cattle and non-lactating dairy cattle only); pour-on treatment for swine = 0.016 oz ai/100 lbs body wt.

<u>Mosquito control use</u>: Aerial Ultra-Low-Volume (ULV) = 0.05 - 0.1 lb ai/acre; Ground ULV = 0.03 lb ai/acre.

Aquaculture use: 0.8 lb ai/acre.

• Annual Poundage: 222,400 to 333,600 lb. a.i.

Mosquito control: 74,400 to 111,600 lb. a.i.

Livestock: 148,000 to 222,000 lb. a.i.

Pour-on: 137,000 to 205,000 lb. a.i. Ear tag: 11,000 to 17,000 lb. a.i.

(Note: Usage data from 1990 -1995)

• **Registrant:** Bayer Corporation, Agriculture Division

Human Health Risk Assessment

Revisions to the Preliminary Human Health Risk Assessment include:

- Human Study Issue: It is current Agency policy to make no final regulatory decision
 based on a human study until a new policy has been developed to ensure that such studies
 meet the highest scientific and ethical standards. In the absence of a policy, the Agency has
 selected doses and endpoints to calculate dietary and non-dietary risk based solely on
 animal studies.
- The dermal absorption factor was changed from 20% to 3%. The dermal absorption factor was re-evaluated due to additional information available regarding the use pattern. The new dermal absorption factor is based on the oral LOAEL of 2.75 mg/kg/day in the oral developmental toxicity study and the dermal LOAEL of 100 mg/kg/day in the 21-day

dermal toxicity study in rabbits based on a common endpoint (cholinesterase inhibition).

- Post-application exposures for adults were calculated in this assessment based on the guidance provided in the Agency's *Standard Operating Procedures For Residential Exposure Assessment* rather than using a lower transfer coefficient of 10,000 cm² for a longer duration.
- Nondietary ingestion risks were calculated in this assessment to account for hand-tomouth and object-to-mouth exposures for toddlers after mosquito control applications.
- Inconsistencies in unit exposure values and exposure scenarios noted in the previous risk assessment for handlers were corrected. The 1998 risk assessment considered handler exposures using three different levels of personal protection including: baseline (applicators wearing long-pants and long-sleeved shirt); using maximum PPE (applicators at baseline with coveralls, gloves, and a respirator); and with the use of engineering controls (e.g., closed cabs, etc.). In this assessment, additional levels of personal protection were considered ranging from a baseline level of protection through the use of engineering controls in every aspect of the application process. Fenthion labels typically require the use of long-pants, long-sleeved shirts, double layer clothing, gloves, and respiratory protection (dust/mist masks with a protection factor of 5). In some cases, however, lower levels of personal protection are required such as when a closed loading system is used or for pilots/applicators in closed cabs.
- PHED data for mixer/loaders of liquids are extrapolated to model ready-to-use pour on applications to animals. Also, airblast application data are used to extrapolate to an applicator during ground ULV mosquito control applications.
- The AgDRIFT model was used to predict deposition after aerial mosquito control applications. AgDRIFT is a product of the SDTF (Spray Drift Task Force) which is a FIFRA task force comprised of pesticide manufacturers, formed to address the spray drift issue.
- The default percentage used to estimate transferable residues of 20 percent of the deposited application rate was reduced to 5 percent of the deposited application rate based on the results of the September 21, 1999 FIFRA SAP meeting in which the panel concurred with an Agency proposal to reduce this value.
- Maximum percent livestock treated numbers were incorporated. 12% beef cattle (9.5% pour-on/spot and 2.5% ear tags), 4% dairy cattle (ear tag only), and 9% swine (pour-on/spot) are treated annually.
- DEEMTM (Dietary Exposure Evaluation Model, based on 1989-1992 USDA food consumption data) was used to generate acute and chronic dietary risk figures. This is a probabilistic assessment which incorporates consumption data generated in USDA's

Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-1992. For chronic dietary risk assessments, the three-day average of consumption for each subpopulation is combined with residues in commodities to determine average exposure in mg/kg/day. For refined acute dietary risk assessments, the entire distribution of consumption events for individuals is multiplied by a distribution of residues (probabilistic analysis, referred to as "Monte Carlo"; risk at 99.9th percentile of exposure reported) to obtain a distribution of exposures in mg/kg/day.

• Typical residential risks from mosquito control use were calculated using corrected average aerial application rates. No correction was necessary at the maximum label rate.

Acute Dietary (Food) Risk

The Agency conducted a probabilistic (tier 3) assessment that considers the distribution of food consumption values and the distribution of residue values found in food. A risk estimate that is less than 100% of the acute Population Adjusted Dose (aPAD, the dose at which an individual could be exposed on any given day and no adverse health effects would be expected, accounting for the safety factor) does not exceed the Agency's risk concern.

The acute dietary (food) risk of fenthion exceeds the Agency's level of concern for the general U.S. population and all population subgroups, including infants and children. Acute risks to the various population subgroups were 340-800% of the aPAD. The most highly exposed subgroup is children 1-6 years, with approximately 800% of the aPAD (at the 99.9th percentile of exposure). Detailed results are shown in Table 1.

- Endpoint is cholinesterase inhibition in plasma during the first week of the monkey oral dosing study (NOAEL = 0.07 mg/kg).
- Uncertainty factor (UF) is 100 (10X for intraspecies variability and 10X for interspecies extrapolation)
- The 10X FQPA safety factor was reduced to 1X because: (1) the data provided no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to fenthion; (2) no evidence of developmental anomalies, including abnormalities in the development of fetal nervous system was observed in the pre- and/or post natal studies; and, (3) there are no data gaps for the critical studies.
- The acute RfD is calculated to be 0.0007 mg/kg/day.
- The Dietary Exposure Evaluation Model (DEEMTM) was used to estimate acute dietary exposure.
- Anticipated residues (ARs) for beef and milk were extrapolated from existing livestock dermal treatment studies since no data were available at the maximum use rate and 21-day

pre-slaughter interval. (The existing studies were conducted using the pour-on application. No studies exist for the ear tag use.) These ARs are higher than current tolerance levels for cattle tissues. While these ARs represent a best estimate using the limited data available, they are an overestimate. ARs are at the tolerance level for pork, based on an appropriate dermal treatment study, and below tolerance level for milk. The ARs for milk are considered reasonable since ear tags are the only dairy cattle use and residues are not expected to be detectable as a result of that use. (½ LOD was not used because ARs were extrapolated.) Residue data are needed for cattle reflecting the maximum application rate and minimum PSI (21 days). All types of treatments (including ear tag treatment) must be represented by adequate residue data. The Agency believes that residues in cattle tissue and milk from the ear tag use would be small compared to residues resulting from the dermal application.

- Fenthion residues in milk were monitored by USDA/PDP in 1996 and 1997; a total of 1,297 samples were analyzed with no detections. PDP data were not used for this assessment because milk is the only commodity that is sampled and because fenthion metabolites of toxic concern are not analyzed.
- Available USDA monitoring data on beef liver did not include all fenthion residues of concern, but qualitatively support the results of the dietary exposure analyses conducted using livestock direct treatment study data.
- The acute critical exposure contribution demonstrates that estimated dietary risk is due largely to potential residues in beef meat and fat and that milk is a minor contributor to acute risk.

Table 1. Acute and Chronic Dietary Exposure/Risk Estimates for Fenthion.

		ssessment 1 %-ile)	Chronic Assessment			
Population Subgroup	Exposure (mg/kg/day)	%aPAD	Exposure (mg/kg/day)	%cPAD		
General US Population	0.003274	470	0.000094	130		
All Infants (<1 yr)	0.004124	590	0.000040	57		
Nursing Infants (<1 year old)	0.003312	470	0.000036	51		
Non-Nursing Infants (<1 yr)	0.004350	620	0.000042	60		
Children (1-6)	0.005627	800	0.000187	270		
Children (7-12 years)	0.003709	530	0.000135	190		
Females (13-19 years)	0.002893	410	0.000087	120		
Females (13-50 years)	0.002390	340	0.000073	100		
Males (13-19 years)	0.002772	400	0.000116	170		
Males (20+ years)	0.002509	360	0.000088	130		

• Acute dietary risks for children 1-6 and 7-12 years fell below the Agency's level of concern (100% aPAD) between the 90th and 95th percentiles of exposure; risks for remaining population subgroups were below the level of concern for acute exposure between the 95th and 97.5th percentiles.

Further Refinements

- Magnitude of residue studies on livestock dermal/ear tag treatments would provide accurate residue numbers for cattle tissue and milk rather than relying on extrapolation from existing livestock dermal treatment studies.
- Studies could also be conducted to determine if residues are reduced during cooking and pasteurization.
- The percent swine treated estimate (9%) is based on a 1994 Nebraska State University survey and, consequently, may be a conservative estimate not accurately representing national usage of fenthion on swine. National swine usage figures would permit additional refinement to the chronic risk assessment, although, compared to beef meat and fat, it is likely that pork commodities do not contribute as significantly to the acute dietary risk.

Chronic Dietary (Food) Risk

Chronic dietary risk is calculated by using the average consumption values for food and average residue values for those foods over a 70-year lifetime. A risk estimate that is less than 100% of the chronic Population Adjusted Dose (cPAD, the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected, accounting for the safety factor) does not exceed the Agency's level of concern.

The chronic dietary (food) risk of fenthion exceeds the Agency's level of concern for the general U.S. population and various population subgroups, excluding infants. The most highly exposed population subgroup was children 1-6 years, at 270% of the cPAD consumed. Infants were the only subgroup for which chronic dietary risk was below the level of concern, at approximately 60% cPAD consumed.

- Endpoint is cholinesterase inhibition in plasma based on the 2-year oral monkey study (threshold NOAEL=0.02 mg/kg/day)
- Uncertainty factor is 300. (10X for interspecies extrapolation; 10X for intraspecies variability; and 3X for the lack of a definitive NOAEL in the critical study). As in the acute dietary assessment, the 10X FQPA safety factor was reduced to 1X.
- The chronic RfD is calculated to be 0.00007 mg/kg/day.
- DEEMTM was used to estimate chronic risk.
- The same upper bound fenthion residue estimates used for the acute dietary analysis for milk and cattle and swine tissue were used for the chronic analysis, as were percent livestock treated numbers.
- Beef fat and meat are the highest contributors to chronic dietary risk for all population groups.
- As in the acute dietary assessment, the residue values are unrefined.

Further Refinements

- The anticipated residues represent a best estimate using the limited data available but may result in an overestimate of the chronic dietary risk. Additional magnitude of residue in livestock commodities studies would further refine the risk.
- National swine usage figures would permit additional refinement to the chronic risk assessment.
- Cooking studies and homogenization could further refine the risk assessment.

Drinking Water Dietary Risk

Drinking water exposure to pesticides can occur through groundwater and surface water contamination. EPA considers both acute (one day) and chronic (multiple year) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. Modeling is carried out in tiers of further refinement, but is designed to provide a high-end estimate of exposure. To determine the maximum allowable contribution from water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then determines a "drinking water level of comparison" (DWLOC) to ascertain whether modeled or monitoring levels exceed this level. The Agency uses DWLOC as a surrogate to capture risk associated with exposure from pesticides in drinking water. Modeling estimates represent an upper bound on concentrations.

- Because dietary risks exceed the Agency's level of concern, DWLOCs were not calculated.
- The potential for exposure to fenthion through drinking water is very low. The Agency believes that the only use that is likely to cause any significant contamination of drinking water is from the mosquito use. There is potential for this use to result in surface water exposure from spray drift.
- Because of rapid degradation of fenthion and the limited use patterns, there are no groundwater concerns about the parent compound.
- The Agency estimated surface water concentrations for fenthion using GENEEC.
- Estimated Environmental Concentrations (EECs) were developed and compared to the PADs. Conservatively modeled fenthion exposure estimates due to drinking water alone (i.e., without considering food sources) indicate that roughly 5-20% of the aPAD and 10-30% of the cPAD could maximally be utilized by residues in drinking water alone.
- There is little concern for adults and children from exposure to fenthion in drinking water because: (I) the EECs utilized in these calculations were derived from conservative, screening-level models; (ii) only minor exposure to surface water is possible due to the application rate and method; and (iii) because the targeted treatment areas are residential which are not significant contributors to drinking water derived from surface water sources.

Residential Risk

Although there are no homeowner uses, residential exposure assessments were conducted to permit risk calculations reflecting the use of fenthion as a residential wide area mosquito adulticide.

- There are no risk concerns for exposure of adults associated with any treatment scenario.
- Combined toddler MOEs resulting from aerial application exceed the Agency's level of concern at the maximum aerial application rate until 8 days post-treatment and until 2 days post-treatment at the average application rate. See Table 2.

Assumptions

- For short-term estimates, the endpoint is cholinesterase inhibition in plasma from the monkey study (oral NOAEL=0.07 mg/kg/day).
- For intermediate-term estimates, the endpoint is cholinesterase inhibition in plasma from the monkey study (oral NOAEL=0.02 mg/kg/day).
- The dermal absorption factor is 3%.
- Nondietary ingestion risks in this assessment were calculated for post-application infant and toddlers exposures because the risks from dermal exposures did not exceed the Agency's level of concern in several scenarios.
- Chemical-specific transferable residue (TR) and deposition data are not available. Therefore, the methods and assumptions were taken from the *SOPs For Residential Exposure Assessment* guidance document. Although the SOPs were initially developed for direct turf applications, the models are used in this assessment to determine if there is a potential concern using a screening level approach. It is estimated that 11.5% of the application rate for aerial ULV and 5% of the application rate for ground-based ULV applications are deposited on turf.
- The default percentage used to estimate transferable residues of 20% of the deposited application rate was reduced to 5% of the deposited application rate based on the results of the September 21, 1999 FIFRA SAP meeting in which the panel concurred with an Agency proposal to reduce this value.
- For post application intermediate-term exposure, it is assumed that the exposed populations are in contact with treated turf for an extended duration on a daily basis over the entire 30 day exposure interval (e.g., 4 hours/day for adults and 2hours/day for toddlers both upper percentile estimates).

- Based on the fenthion use patterns and current labeling, four major post-application
 exposure scenarios were modeled using a surrogate approach for each application method
 (i.e., aerial and ground). Two of these scenarios are assessments of exposure to adults
 while the remaining two scenarios were assessments of exposures to toddlers. The four
 scenarios are:
 - (1) adults involved in a high exposure activity (e.g., heavy yard work) at the typical Florida mosquito control application rate;
 - (2) adults involved in a high exposure activity (e.g., heavy yard work) at the label maximum mosquito control application rate;
 - (3) toddlers involved in a high exposure activity (e.g., rolling/playing on lawn) at the typical Florida mosquito control application rate; and
 - (4) toddlers involved in a high exposure activity (e.g., rolling/playing on lawn) at the label maximum mosquito control application rate.
- Due to a lack of scenario-specific exposure data, the Agency has calculated unit exposure values for adults using a surrogate dermal transfer coefficient based on the use of the Jazzercize protocol. For exposure assessment purposes, the Agency has used 20 minutes of Jazzercize to represent each hour of activities that contribute to dermal exposure.
- The Agency used the Spray Drift Task Force model for predicting deposition from aerial applications (i.e., AgDRIFT) to determine how much material deposits in residential areas after aerial applications and published data to determine how much material deposits in residential areas after ground-fogger applications.
- Calculations were completed using the maximum application rates for ground-based and aerial applications (i.e., 0.03 and 0.10 lb ai/A, respectively). Additionally, calculations were completed using the average Lee County, Florida application rates (i.e., 0.016 and 0.050 lb ai/A, respectively). The overall application rate, regardless of application method, in Florida appears to be 0.037 lb ai/acre. This value has also been used in the assessment for risk characterization purposes.
- After these values were determined, the risks for adults and toddlers were calculated using guidance included in the Agency's *Standard Operating Procedures For Residential Exposure Assessment* and guidance provided at the recent meeting of the FIFRA Science Advisory Panel on residential exposure issues.

TAB	TABLE 2. COMBINED MOES ATTRIBUTABLE TO TODDLER EXPOSURES IN AREAS PREVIOUSLY TREATED WITH FENTHION USING AERIAL ULV EQUIPMENT													
DAT	TODDLER DERMAL EXPOSURE MOES		TODDLER HAND-TO-MOUTH MOES		OBJECT-T	DLER O-MOUTH DES	TODDL INGESTIC	ER SOIL ON MOES	TODDLER COMBINED MOES					
	AVERAGE APPL. RATE	MAXIMUM APPL. RATE	AVERAGE APPL. RATE	MAXIMUM APPL. RATE	AVERAGE APPL. RATE	MAXIMUM APPL. RATE	AVERAGE APPL. RATE	MAXIMU M APPL. RATE	AVERAGE APPL. RATE	MAXIMUM APPL. RATE				
0	1670	935	91	51	2907	1628	216908	121469	83.6	46.8				
1	1855	1039	101	57	3230	1809	241009	134965	92.9	52.0				
2	2061	1154	112	63	3588	2009	267788	149961	103.3	57.8				
3	2290	1283	125	70	3987	2233	297542	166624	114.7	64.2				
4	2545	1425	138	78	4430	2481	330603	185137	127.5	71.4				
5	2827	1583	154	86	4922	2756	367336	205708	141.6	79.3				
6	3142	1759	171	96	5469	3063	408151	228565	157.4	88.1				
7	3491	1955	190	106	6077	3403	453502	253961	174.9	97.9				
8	3879	2172	211	118	6752	3781	503891	282179	194.3	108.8				
9	4310	2413	234	131	7502	4201	559878	313532	215.9	120.9				
10	4788	2681	260	146	8336	4668	622087	348369	239.9	134.3				
AVG.	1537	861	84	47	2677	1499	199739	111854	77.0	43.1				

Further Refinements

- The *Outdoor Residential Exposure Task Force* (ORETF) are to conduct studies which will enable the Agency to evaluate residential exposures due to contact with treated turf (i.e., to generate appropriate activity pattern and transfer coefficient data).
- The registrant could develop a strategy to generate chemical-specific transferable residue data to be used in conjunction with the ORETF database in order for the Agency to complete any exposure/risk assessment.

Aggregate Risk

Under the Food Quality Protection Act, the Agency considers contributions to risk from various exposure sources, specifically food, drinking water, and residential uses of a pesticide.

Acute Aggregate Exposure and Risk

• The Agency is able to quantitate the food sources of dietary exposure and residential exposure; dietary exposure through drinking water has only been estimated using models. Acute dietary (food only) risks exceed the Agency's level of concern as the most exposed population subgroup, children (1-6 years), has a risk that is 800% of the aPAD based on unrefined residue values. Based on EECs generated via modeling, the potential exists for relatively small additional contributions to the acute aggregate risk from surface water sources of drinking water in Florida. Thus, there is concern for acute aggregate risk due to fenthion use.

Aggregate Short-term and Intermediate-term Exposures and Risks

• There are food and water sources of dietary exposure as well as residential exposures to fenthion based on the current use pattern. Chronic dietary risk from food sources exceeds the Agency's level of concern with the most highly exposed population subgroup, again, being children (1-6 years) at 270% of the cPAD. Drinking water sources could possibly contribute comparatively small levels of additional dietary exposure and, hence, risk in Florida. Combined residential dermal and nondietary ingestion exposures following aerial mosquito adulticide treatments result in risks of concern to toddlers; toddler MOEs did not exceed the uncertainty factor of 100 until 2 days after application at the average application rate and until 8 days after application at the maximum application rate (risks would not be of concern using the human study as support). The Agency is, therefore, concerned about short-term and intermediate-term aggregate risk associated with the use of fenthion.

Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, or applying a pesticide, and reentering a treated site. Worker risk is measured by a Margin of Exposure (MOE). For fenthion, MOEs that are less than 100 (for short-term exposure (1-7 days)) and 300 (for intermediate-term exposure (7 days to several months)) exceed the Agency's level of concern.

Exposure Scenarios

EPA has determined that exposure to pesticide handlers is likely during the occupational use of fenthion in a variety of environments. The major exposure scenarios are:

- (1a) mixing/loading liquids for mosquito control fixed-wing aerial applications to 7500 acres per day (see further explanation below);
- (1b) mixing/loading liquids for mosquito control ground-fogger applications to 3000 acres per day (see further explanation below);
- (2) loading granular materials for mosquito control fixed-wing aerial applications to 80 or 800 acres per day (see further explanation below);
- (3) applying liquids using aerial equipment (includes both ULV and thermal fogger) for mosquito control applications to 7500 acres per day (see further explanation below);
- (4) applying liquids using ULV ground-fogger equipment for mosquito control to 3000 acres per day (see further explanation below);
- (5) applying granulars using aerial equipment for mosquito control applications to 80 or 800 acres per day (see further explanation below);
- (6) applying the ready-to-use solutions to livestock (cattle and swine) to 200 animals per day;
- (7) applying cattle ear tags to 200 animals per day;
- (8) mixing/loading/applying liquids to livestock via ladeling to 200 animals per day;
- (9) loading/applying granulars for ground-based mosquito larvicide control applications to 5 acres per day;
- (10) mixing/loading/applying liquids for aquaculture using low pressure handward sprayers to a single 2.5 or 5 acre pond per day;
- (11) mixing/loading/applying liquids for aquaculture using backpack sprayers to a single 2.5 or 5 acre pond per day;
- (12) flagging during aerial application of liquids to 7500 acres per day (see further explanation below); and
- (13) flagging during aerial application of granulars to 80 or 800 acres per day (see further explanation below).

Assumptions

• For short- and intermediate-term risk assessment, the doses used were 0.07 and 0.02 mg/kg/day, respectively, from the monkey study in which plasma cholinesterase inhibition was the endpoint (threshold NOAEL/LOAEL was 0.02 mg/kg/day).

- Dermal absorption was assumed to be 3%.
- An average occupational work day interval represents 8 hours per workday.
- No chemical-specific handler exposure data were submitted in support of the reregistration of fenthion. As a result, the Pesticide Handlers Exposure Database (PHED) was used to complete all occupational handler risk assessments.
- For aerial ULV applications, it is estimated that an applicator would treat 7500 acres per day. For ground applications, 3000 acres.
- All animal use scenario calculations were based on 200 animals treated daily (i.e., approximately 1 animal every 2.4 minutes over an 8 hour day). Animal assessments were based on cattle since they are larger than swine. Treated cattle were assumed to weigh 600 pounds.
- Average body weight of an adult handler is 70 kg. This body weight is used in all assessments since the endpoints of concern are not sex-specific (i.e., the cholinesterase inhibition could be assumed to occur in males or females).
- All handler calculations were completed using typical (if available) and maximum labeled application rates for each scenario.

Occupational Risk

- The risks exceed the Agency's level of concern for loaders when using liquid formulations in preparation for mosquito adulticide applications of fenthion, and pilots and ground applicators during adulticide applications.
- For mosquito larvicide applications, the level of concern is exceeded for pilots during aerial application and for individuals completing ground applications.
- The Agency believes that the use of human flaggers is rare during mosquito control applications but completed an assessment for these individuals to account for other people that may be exposed in a similar manner (e.g., ground observers). The risks associated with these jobs exceeded each of the Agency's uncertainty factors during granular applications but not for liquid applications.
- For the treatment of food animals, the Agency has concerns for the ladle-on and ear tag placement exposures due to a lack of data with which to complete the assessment.
- Additionally, the Agency has risk concerns for the use of fenthion in aquaculture. Details of the occupational risk calculations are presented in Tables 3 and 4.

		TABL	E 3: FEN	ITHION MO	Es ATTRIBUT	ГАВLЕ ТО COMBI	NED SHORT-TE	ERM DERMAL AN	ND INHALATION	EXPOSURES			
SCEN.	SCEN. DESCRIPTOR	CROP TYPE OR TARGET	EXPOSURE FACTORS		SUMMARY MOEs FOR COMBINATIONS OF DERMAL AND INHALATION PROTECTIVE MEASURES								
			RATE	ACRES OR GALLON S	BASELINE (TABLE 2)	SINGLE LAYER, GLOVES & NO RESPIRATOR (TABLES 2 &3)	LAYER, GLOVES & PF 5 RESPIRATOR	SINGLE LAYER, GLOVES & PF 10 RESPIRATOR (TABLES 3 & 4)	DOUBLE LAYER, GLOVES & NO RESPIRATOR (TABLES 2 & 4)	DOUBLE LAYER, GLOVES & PF 5 RESPIRATOR (TABLES 3 & 4)	DOUBLE LAYER, GLOVES & PF 10 RESPIRATOR (TABLE 4)	ENG. CONTROLS (TABLE 5)	
						OCCUPATION	AL MIXER/LOAD	DERS					
1a	Mixing/loading Liquids for	Mosquito Adulticide	0.1	7500	0.1	3.5	7.0	8.1	3.8	8.7	10.4	19.2	
	Aerial Application	Mosquito Adulticide	0.056	7500	0.1	6.2	12.5	14.4	6.8	15.6	18.5	34.2	
1b	Mixing/loading Liquids for	Mosquito Adulticide	0.03	3000	0.6	28.8	58.5	67.2	31.8	72.6	86.4	159.7	
	Ground Fogger Application	Mosquito Adulticide	0.016	3000	1.2	54.0	109.8	126.0	59.7	136.1	162.0	299.4	
2	Loading Granulars for Aerial Application	Mosquito Larvicide	0.1	800	31.4	32.1	112.0	162.5	34.0	138.6	225.2	1568.9	
		Mosquito Larvicide	0.056	800	56.0	57.4	200.0	290.1	60.7	247.5	402.1	2801.6	
		Mosquito Larvicide	0.1	80	313.8	321.2	1119.7	1624.7	339.9	1385.7	2251.8	15689.0	
		Mosquito Larvicide	0.056	80	560.3	573.5	1999.5	2901.2	607.0	2474.5	4021.1	28016.1	
						OCCUPATIO	NAL APPLICATO	ORS					
3	Aerial Application of	Mosquito Adulticide	0.1	7500	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	30.0	
	Liquid Sprays	Mosquito Adulticide	0.056	7500	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	53.5	
4	Ground Fogger Application	Mosquito Adulticide	0.03	3000	3.6	4.7	6.7	7.1	4.9	7.3	7.7	53.4	
		Mosquito Adulticide	0.016	3000	6.7	8.7	12.6	13.3	9.2	13.6	14.5	100.1	
5	Aerial Application of	Mosquito Larvicide	0.1	800	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	45.3	
	Granulars	Mosquito Larvicide	0.056	800	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	81.0	
		Mosquito Larvicide	0.1	80	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	453.4	

		TABI	E 3: FEN	ITHION MO	Es ATTRIBUT	ГАВLЕ ТО COMBI	NED SHORT-TE	ERM DERMAL AN	ND INHALATION	EXPOSURES			
SCEN.	SCEN. DESCRIPTOR	CROP TYPE OR TARGET	-	SURE TORS	SUMMARY MOEs FOR COMBINATIONS OF DERMAL AND INHALATION PROTECTIVE MEASURES								
			RATE	ACRES OR GALLON S	BASELINE (TABLE 2)	SINGLE LAYER, GLOVES & NO RESPIRATOR (TABLES 2 &3)	SINGLE LAYER, GLOVES & PF 5 RESPIRATOR (TABLE 3)	SINGLE LAYER, GLOVES & PF 10 RESPIRATOR (TABLES 3 & 4)	DOUBLE LAYER, GLOVES & NO RESPIRATOR (TABLES 2 & 4)	DOUBLE LAYER, GLOVES & PF 5 RESPIRATOR (TABLES 3 & 4)	DOUBLE LAYER, GLOVES & PF 10 RESPIRATOR (TABLE 4)	ENG. CONTROLS (TABLE 5)	
		Mosquito Larvicide	0.056	80	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	809.6	
6	Ready-to-Use Package For Livestock	Fly Control	0.008	200	33.1	1543.2	3136.2	3600.8	1705.7	3888.9	4629.6	Not Feasible	
7	Ear Tags For Cattle	Fly Control	0.013	200	No Data	No Data	No Data	No Data	No Data	No Data	No Data	Not Feasible	
					OCC	UPATIONAL MIX	ER/LOADER/AP	PLICATORS					
8	Ladel On For Livestock	Fly Control	0.004	200	No Data	No Data	No Data	No Data	No Data	No Data	No Data	Not Feasible	
9	Ground-based Granular Application	Mosquito Larvicide	0.1	5	27.1	28.7	33.6	34.4	42.0	53.3	55.2	Not Feasible	
10	Low Pressure Handwand	Dragonfly Larvicide	0.8	5	0.4	28.6	64.8	77.0	29.8	71.6	86.9	Not Feasible	
	Application of 95% Liquid	Dragonfly Larvicide	0.8	2.5	0.8	57.1	129.6	154.1	59.6	143.3	173.8	Not Feasible	
11	Backpack Application of	Dragonfly Larvicide	0.8	5	No Data	11.7	15.1	15.7	15.7	22.7	24.0	Not Feasible	
	95% Liquid	Dragonfly Larvicide	0.8	2.5	No Data	23.3	30.2	31.4	31.4	45.4	48.0	Not Feasible	
						FL	AGGERS						
12	Flagging For Aerial	Mosquito Adulticide	0.1	7500	9.6	9.2	15.2	16.5	9.6	16.3	17.9	480.4	
	Application of Liquid Sprays	Mosquito Adulticide	0.056	7500	17.2	16.4	27.1	29.5	17.2	29.2	32.0	857.8	
13	Flagging For Aerial	Mosquito Larvicide	0.1	800	261.8	309.3	785.3	972.2	340.3	1020.8	1361.1	13087.6	
	Application of Granulars	Mosquito Larvicide	0.056	800	467.4	552.4	1402.2	1736.1	607.6	1822.9	2430.6	23370.7	

		TABLE 4:	FENTHI	ON MOEs AT	TRIBUTABLI	E TO COMBINE	D INTERMEDIA	TE-TERM DERMA	L AND INHALATI	ON EXPOSURES			
SCEN.	SCEN. DESCRIPTOR	CROP TYPE OR TARGET	EXPOSURE FACTORS		SUMMARY MOEs FOR COMBINATIONS OF DERMAL AND INHALATION PROTECTIVE MEASURES								
			RATE	ACRES OR GALLONS	BASELINE (TABLE 2)	(TABLES 2 &3)	(TABLE 3)	SINGLE LAYER, GLOVES & PF 10 RESPIRATOR (TABLES 3 & 4)	DOUBLE LAYER, GLOVES & NO RESPIRATOR (TABLES 2 & 4)	DOUBLE LAYER, GLOVES & PF 5 RESPIRATOR (TABLES 3 & 4)	DOUBLE LAYER, GLOVES & PF 10 RESPIRATOR (TABLE 4)	ENG. CONTROLS (TABLE 5)	
				_		OCCUPATION	NAL MIXER/LOA	DERS					
1a	Mixing/loading Liquids for Aerial	Mosquito Adulticide	0.1	7500	0.02	1.0	2.0	2.3	1.1	2.5	3.0	5.5	
	Application	Mosquito Adulticide	0.056	7500	0.04	1.8	3.6	4.1	1.9	4.4	5.3	9.8	
1b	Mixing/loading Liquids for Ground	Mosquito Adulticide	0.03	3000	0.18	8.2	16.7	19.2	9.1	20.7	24.7	45.6	
	Fogger Application	Mosquito Adulticide	0.016	3000	0.33	15.4	31.4	36.0	17.1	38.9	46.3	85.5	
2	Loading Granulars for Aerial Application	Mosquito Larvicide	0.1	800	8.97	9.2	32.0	46.4	9.7	39.6	64.3	448.3	
		Mosquito Larvicide	0.056	800	16.01	16.4	57.1	82.9	17.3	70.7	114.9	800.5	
		Mosquito Larvicide	0.1	80	89.65	91.8	319.9	464.2	97.1	395.9	643.4	4482.6	
		Mosquito Larvicide	0.056	80	160.09	163.9	571.3	828.9	173.4	707.0	1148.9	8004.6	
						OCCUPATIO	NAL APPLICAT	ORS					
3	Aerial Application of Liquid Sprays	Mosquito Adulticide	0.1	7500	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	8.6	
		Mosquito Adulticide	0.056	7500	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	15.3	
4	Ground Fogger Application	Mosquito Adulticide	0.03	3000	1.02	1.3	1.9	2.0	1.4	2.1	2.2	15.3	
		Mosquito Adulticide	0.016	3000	1.91	2.5	3.6	3.8	2.6	3.9	4.1	28.6	
5	Aerial Application of Granulars	Mosquito Larvicide	0.1	800	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	13.0	
		Mosquito Larvicide	0.056	800	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	23.1	
		Mosquito Larvicide	0.1	80	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	129.5	

		TABLE 4:	FENTHI	ON MOEs AT	TRIBUTABLE	E TO COMBINE	D INTERMEDIA	TE-TERM DERMA	L AND INHALATI	ON EXPOSURES				
SCEN.	SCEN. DESCRIPTOR	CROP TYPE OR TARGET		OSURE CTORS	SUMMARY MOEs FOR COMBINATIONS OF DERMAL AND INHALATION PROTECTIVE MEASURES									
			RATE	ACRES OR GALLONS	BASELINE (TABLE 2)	SINGLE LAYER, GLOVES & NO RESPIRATOR (TABLES 2 &3)	SINGLE LAYER, GLOVES & PF 5 RESPIRATOR (TABLE 3)	SINGLE LAYER, GLOVES & PF 10 RESPIRATOR (TABLES 3 & 4)	LAYER, GLOVES & NO	DOUBLE LAYER, GLOVES & PF 5 RESPIRATOR (TABLES 3 & 4)	DOUBLE LAYER, GLOVES & PF 10 RESPIRATOR (TABLE 4)	ENG. CONTROLS (TABLE 5)		
		Mosquito Larvicide	0.056	80	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	231.3		
6	Ready-to-Use Package For Livestock	Fly Control	0.0084	200	9.45	440.9	896.1	1028.8	487.3	1111.1	1322.8	Not Feasible		
7	Ear Tags For Cattle	Fly Control	0.013	200	No Data	No Data	No Data	No Data	No Data	No Data	No Data	Not Feasible		
					OCCI	JPATIONAL MIX	KER/LOADER/AI	PPLICATORS						
8	Ladel On For Livestock	Fly Control	0.004	200	No Data	No Data	No Data	No Data	No Data	No Data	No Data	Not Feasible		
9	Ground-based Granular Application	Mosquito Larvicide	0.1	5	7.73	8.2	9.6	9.8	12.0	15.2	15.8	Not Feasible		
10	Low Pressure Handwand Application of 95% Liquid	Dragonfly Larvicide	0.8	5	0.12	8.2	18.5	22.0	8.5	20.5	24.8	Not Feasible		
		Dragonfly Larvicide	0.8	2.5	0.23	16.3	37.0	44.0	17.0	40.9	49.6	Not Feasible		
11	Backpack Application of 95%	Dragonfly Larvicide	0.8	5	No Data	3.3	4.3	4.5	4.5	6.5	6.9	Not Feasible		
	Liquid	Dragonfly Larvicide	0.8	2.5	No Data	6.7	8.6	9.0	9.0	13.0	13.7	Not Feasible		
						FI	LAGGERS							
12	Flagging For Aerial Application of	Mosquito Adulticide	0.1	7500	2.75	2.6	4.3	4.7	2.7	4.7	5.1	137.3		
	Liquid Sprays	Mosquito Adulticide	0.056	7500	4.90	4.7	7.8	8.4	4.9	8.3	9.1	245.1		
13	Flagging For Aerial Application of	Mosquito Larvicide	0.1	800	74.79	88.4	224.4	277.8	97.2	291.7	388.9	3739.3		
	Granulars	Mosquito Larvicide	0.056	800	133.55	157.8	400.6	496.0	173.6	520.8	694.4	6677.4		

Incident Reports

A fenthion human incident review was conducted by the Agency in 1996. Data from the national Poison Control Centers (PCCs) over the years 1985-92 reveal 52 cases of occupational exposure to fenthion and 417 cases of nonoccupational exposure, over 95% of which were due to fenthion alone. From 1993-96, PCCs reported 13 occupational exposures; of these, four had minor symptoms, one had moderate symptoms, six were seen in a health care facility, and none were hospitalized. There were six reports (three involving fenthion alone) of human incidents by the California Department of Pesticide Regulation/California Pesticide Illness Surveillance Program between 1982 and 1993; of the three involving fenthion alone (one in1982, 1983, and 1987), two resulted in systemic effects and resulted from spray blowing back in the applicator's face during mosquito treatments. The other involved a veterinary technician who spilled fenthion on her smock.

Further Refinements

• Fenthion-specific handler studies (including animal uses) for short- and intermediate-term dermal and inhalation exposure would further refine the risk.

Ecological Risk Assessment

Nontarget Terrestrial Animal Risk

- Fenthion is very highly toxic to avian species on an acute oral basis and slightly to highly toxic to avian species on a subacute dietary basis.
- The Agency's level of concern is exceeded for endangered bird species on an acute and chronic basis from the mosquito adulticide use.
- Fenthion has displayed numerous instances of secondary toxicity to birds. Secondary risk may occur via dermal contamination of birds exposed to mosquito spray treatments or via ingestion of contaminated food sources (e.g., grass, seeds, insects). It is possible that the livestock use poses some risk to birds that perch on recently treated livestock through dermal contact with the bird's feet and feathers.

Nontarget Aquatic Animal Risk

- Highly to very highly toxic to estuarine/marine invertebrates on an acute basis.
- Moderately toxic to estuarine/marine fish on an acute basis.

• The level of concern is exceeded for endangered species of estuarine/marine invertebrates on an acute and chronic basis from the mosquito adulticide use. The livestock use is not expected to contribute to the risk to aquatic organisms.

Summary of Public Comments

The only comments that were received were from the registrant, Bayer. The Agency reviewed these comments and the only substantive revision made to the risk assessment is as follows:

• Bayer reiterated their belief that the Agency is using the wrong average application rate for fenthion in Lee County, Florida. The Agency used an average application rate of 0.056 lb ai/acre in the risk assessment. Bayer maintains that the correct average mosquito application rate for fenthion in Lee County, Florida is 0.029 lbs ai/acre. Bayer's assertion that the average Lee Co. rate was 0.029 lb ai/acre is correct; however, in the Agency's preliminary risk assessment, we used the average rate for all three Florida counties in which applications were made. Therefore, the average rate has been corrected slightly (from 0.056 to 0.05 lb ai/acre). This results in an 11% reduction in residential exposure following aerial mosquitocide applications.